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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
08/104,529	08/12/93	CLASSEN	J CLASSEN1

BROWDY & NEIMARK
419 SEVENTH STREET, N.W.
WASHINGTON DC 20004

18N2/0219

EXAMINER	
VOGEL, N	
ART UNIT	PAPER NUMBER
1805	22

DATE MAILED:

02/19/97

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.

08/104,529

Applicant(s)

Classen

Examiner

Nancy T. Vogel

Group Art Unit

1805



☒ Responsive to communication(s) filed on Nov 22, 1996

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 2-14, 16-18, 21-26, 28-34, 37, and 39-59 is/are pending in the application.

Of the above, claim(s) 39 and 40 is/are withdrawn from consideration.

☒ Claim(s) 21-26, 28-34, 37, and 50-57 is/are allowed.

☒ Claim(s) 2-14, 16-18, 41, 43-49, 58, and 59 is/are rejected.

☒ Claim(s) 42 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. Claims 39 and 40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 8.

It is noted that applicants cannot amend withdrawn claims. Therefore, the amendments to claims 39-40 have not been entered.

2. Claim 2-14, 16-18, 41, 43-49, 58-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods which reduce the incidence of diabetes mellitus or SLE, does not reasonably provide enablement for methods which reduce the incidence of any chronic immune related disease or any autoimmune disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The claims methods for the reduction of incidence of any chronic immune related disease or any autoimmune disease. It is noted that the terms "chronic immune mediated disorder" and "autoimmune disease" comprises perhaps hundreds or thousands of diseases ranging from hay fever to cancer. Although applicants have provided evidence that reduction of diabetes mellitus type I and SLE incidence can be reduced, it is maintained that the mechanisms by which immune related diseases occur are widely varying, and there is no predictability regarding any one treatment's effect on other immune related disease. It is maintained that it would require undue experimentation to determine vaccination schedules, and types and amounts of immunogens, which would have the claimed effect of reduction of incidence of any autoimmune disease or

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chronic immune-mediated disorder, due to the lack of guidance in the specification and the very large numbers of possible variations embodied by the claims. Therefore, the claims should be limited to methods which reduce the incidence of diabetes mellitus or SLE.

3. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the listed immunogens other than a malaria or HIV immunogen, does not reasonably provide enablement for a method of immunizing against malaria or HIV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The rejection is maintained for the reasons made of record in the previous Office action. Applicants have argued that the thrust of the instant invention is not vaccination against malaria and HIV, but rather reducing the incidence of autoimmune disease. However, it is maintained that the instant claim recites immunization against malaria and HIV, as acknowledged by applicants. Therefore, the rejection is maintained.

4. Claims 41, 43-46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferreri et al., Lee et al., Barrett et al., Halsy et al., Huang et al., or Harris et al. (U.S. Pat. No. 4,152,415) (all previously cited).

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This rejection is maintained for the reasons set forth in the previous Office action. Applicants have argued that the written instructions recited in the claims must be given equal consideration to the actual product, citing In re Gulack, 217 USPQ 401,405 (Fed. Cir. 1983). However, it is maintained that In re Gulack states that weight is given printed material if there is a functional relationship to the substrate. Gulack involved a band or ring with digits imprinted on the band, in which said digits bear a functional relationship to the band itself, i.e. they display various aspects of number theory, or can be used to perform magic tricks. In contrast, the written material in the instant claims are simply instructions as to how to use the product, which constitute an intended use, and is given little weight. Therefore, applicants' arguments are not found convincing and the rejection is maintained.

Claim 42 is objected to as being dependent upon a rejected base claim

Claims 21-26, 28-34, 37, 50-57 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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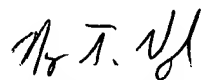
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (703) 308-0278. The examiner can normally be reached on Monday through Wednesday from 7:30AM to 3:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mindy Fleisher, can be reached on (703) 308-0407. Certain papers related to this application may be submitted to Art Unit 1805 by facsimile transmission. Papers should be faxed to Art Unit 1805 via the PTO FAX Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see C.F.R. 1.6(d)). The Art Unit 1805 FAX number is (703) 308-0294.

NOTE: If Applicants **does** submit a paper by Fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


NANCY T. VOGEL
PRIMARY EXAMINER
GROUP 1800